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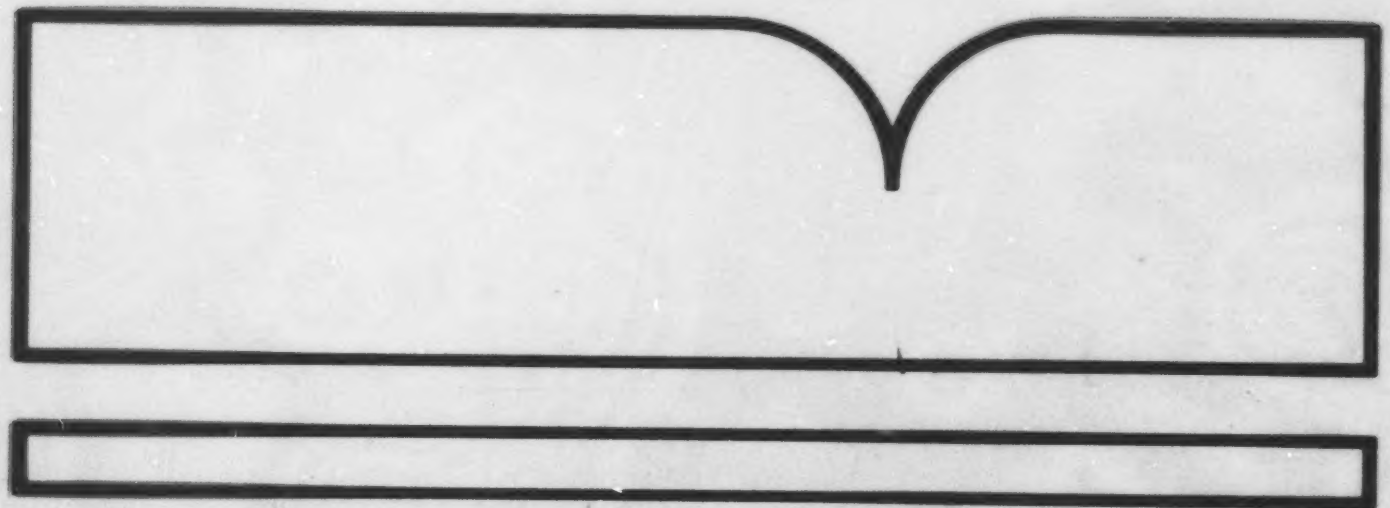

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16. Abstract (Limit: 200 words)

The Data Reporting Guideline (DRG) for Directions for Use, Series 171-3, gives guidance to pesticide registrants on the contents of the section of a residue chemistry registration submittal on the directions for the application of a pesticide and its use restrictions. Following this guidance will increase the efficiently of the Agency in reviewing submissions. It clarifies sections in the existing Pesticides Assessment Guidelines, Subdivision O. It provides guidance in expressing use directions which should include the dosage, frequency, timing of applications as well as the mode of delivery. Data submitters can use the DRG in preparing their reports for submission to EPA to meet 40 CFR 158 requirements for the registration of pesticides.

The DRG for Series 171-3, Directions for Use is only one of a number of DRG's published by the National Technical Information Service as an addendum to Subdivision O of the Pesticide Assessment Guidelines.

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PESTICIDE ASSESSMENT GUIDELINES

SUBDIVISION O

RESIDUE CHEMISTRY

Series 171-3

Directions For Use

ADDENDUM 6 ON DATA REPORTING

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Subdivision O - Directions for Use

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PESTICIDE ASSESSMENT GUIDELINES

RESIDUE CHEMISTRY

Directions For Use

Subdivision O, Series 171-3

DATA REPORTING

INTRODUCTION

A. Purpose

The Directions for Use are required by 40 CFR 162.10 to support the registration of any pesticide intended for use on a food or feed crop under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

The Directions for Use form a part of the requirements for the registration, reregistration, or amended registration of pesticides intended for use on agricultural commodities under sections 408 and 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended. Further regulatory support is provided in 40 CFR Parts 158.125, 162, and 180.

B. Objective

The Directions for Use provide the user or pesticide applicator with the appropriate methods for the treatment of soils, crops, water, establishments, livestock, and livestock areas with the pesticide. These uses are designed to provide effective and efficacious means for treatments with pesticides. The Directions for Use are essential to an adequate evaluation of the residue data. As a result, such Directions must be clear and reflect those uses expected to be effective against the target pest and result in residues in crops. These data aid in the assessment of the exposure of the public to pesticide chemicals. Consequently, the uses should be supported by residue data which reflect the proposed conditions of use.

This Data Reporting Guideline (DRG) is designed to aid the petitioner/registrant in the data/information collection/organization process. While other DRGs provide formats for study reports, this DRG provides guidance on expressing use directions (for the readers' convenience, the guidance has been presented in an outline format which addresses the items/topics to be covered). Data submitters are strongly encouraged to use this DRG to increase the efficiency of the registration and reregistration processes. It pertains to the substance of the data report. PR Notice 86-5, effective November 1, 1986 and available

from the Office of Pesticide Programs, pertains to physical formatting of reports referred to as "studies" and submittal packages. Some of its requirements are mandatory.

RESPONSE TO PUBLIC COMMENTS

The purpose of this section is to acknowledge and address the concerns expressed in the letters of comment received by the Agency in response to the public notice in the FEDERAL REGISTER of March 25, 1987 (52 FR 9536). Of the seven responses received, two commented on the Directions for Use Data Reporting Guideline.

This addendum to the Pesticide Assessment Guidelines [Subdivision O] is to be considered an all-encompassing document. EPA recognizes there are sections in the addendum which do not apply in all cases. Therefore, registrants should exercise scientific judgment in deciding which portions are germane to a specific data submission.

This DRG is not intended to introduce new data requirements or revisions into the Pesticide Assessment Guidelines [Subdivision O] nor is it intended for use by Agency data reviewers as a mere checklist. It is intended to clarify ambiguities in interpretation of those existing Guidelines, and to organize the submission of data to facilitate the review process.

The Residue Chemistry Branch (RCB) has reviewed the comments submitted by the registrants and/or committees in regard to the DRG. The comments submitted are addressed as follows (the page numbers in the comments refer to the page numbers in the document available for public comment and the corresponding section in this document has been provided in brackets):

Comment:

"The expression of formulations and inerts (page 2) [B.] is incorrect. Formulation inerts are those inerts required to have the biologically active material function effectively in field use. Adjuvants are materials which may be added at the time of use."

Response:

The term inert ingredient is defined under 40 CFR §162.3(t) as "all ingredients which are not active ingredients . . . ." In order to avoid any confusion in the use of the term adjuvant, the last sentence has been changed to read, "The inert ingredients are all ingredients which are not active ingredients [40 CFR 162.3(t)] and serve such functions as stickers or spreaders."

Comments:

"The paragraph at the top of page 3 [C. 1.] and points 1 and 2 under use restrictions on page 6 [D. 1. and 2.] are nearly identical. We would suggest that all be included under the Use Restrictions sections only. Listing restrictions in more than one place on the report may be confusing

in that each list may not be complete. The minimum interval between successive applications, if relevant, could appear in the general application information as well."

"On page 3, the first sentence of the last paragraph under 'Full-coverage sprays' [C. 1. b.] may cause some confusion. We suggest it be changed to '. . . should include the spray concentration or active ingredient per acre and the spray volume per acre.'"

Response:

We agree that the paragraph at the top of page 3 [C. 1.] and points 1 and 2 under Use Restrictions on page 6 [D. 1. and 2.] are similar. The paragraph at the top of page 3 is a general statement to help explain the Application of Pesticides [Application Directions] introduced on page 2 [C. 1.]. The use restrictions on page 6, points 1 and 2 (D. 1. and 2.] expand and help to clarify the areas under which they are listed. These clarifications help to broaden the understanding of the paragraphs involved. This also applies to information on the minimum interval between treatments.

We do not agree that all items should be included under the Use Restrictions section only. Therefore, no change is warranted.

We agree that the suggested change for page 3 [C. 1. b.] aids in clarification and have revised the document accordingly.

GUIDELINE

TITLE/COVER PAGE

Title page and additional documentation requirements (i.e., requirements for data submission and statement of data confidentiality claims), if relevant to the report, should precede the content of the report discussed below. These current requirements are described in PR Notice 86-5 published by the Office of Pesticide Programs on July 29, 1986.

DIRECTIONS FOR USE

The Directions for Use should include the dosage, frequency, timing of application, as well as the mode of delivery. The Directions should also show which formulation is to be used, a preharvest interval (PHI) if needed, or other limitations as needed. Each of the essential factors of Use Directions are discussed below.

A. Crops

All crops (field and/or orchard) which are to be treated with the pesticide formulation should be clearly identified. The crops listed should be consistent with those for which tolerances have been proposed or exemptions requested.

The crop groupings represent exceptions to the foregoing discussion (see 40 CFR 180.34). A tolerance may be proposed for a collection of related crops (crop group) without Use Directions for each individual crop in the group. Representative crops from the crop group may be provided as a minimum requirement for data purposes. However, the Use Directions for all crops in the group must be similar before the specific crop(s) is (are) registered under FIFRA.

B. Formulations

The pesticide chemicals which are to be used are formulated as dusts, liquids, or granular forms. The formulation to be used must be expressed quantitatively in terms of its active ingredient and its inert ingredients. The inert ingredients are all ingredients which are not active ingredients [40 CFR 162.3(t)] and serve such functions as stickers or spreaders.

C. Application Directions

1. Field and Orchard Applications

The application of dusts, sprays, and granular formulations are to be expressed in terms of pounds of active ingredient per acre (lb ai/A). For band or row treatments, the use should indicate if the pounds per acre rate refers to the area treated or to the entire field.

The maximum number of applications permitted per growing season or per year should be provided. Additionally, the minimum interval between successive applications and the minimum interval between the last application and harvest should be provided.

a. Orchard Treatments

The application of pesticides to orchards generally requires more attention than other crops due to the variations in tree size. The various modes of application are discussed below.

i. Full-Coverage Sprays

For full-coverage sprays to orchards, the dosage should be expressed as pounds active ingredient per 100 gallons spray solution to runoff. The dosage is expressed in this manner because of the variation in the quantity of active ingredient applied per acre as a result of the variation in the size of the trees.

ii. Concentrated Sprays

In the case of concentrated orchard sprays, the amount

of active ingredient applied per acre should also be related to tree size. Usually this can be achieved by specifying the same or less active ingredient per acre as the amount which would be applied using a full coverage spray.

iii. Options

In order to lessen the possibility of excess treatment, some options include information on the label which indicate that smaller trees should be treated with less volume of solution and thus less active ingredient per acre. Alternatively, data could be provided to show the maximum likely residues to be expected due to treatment with the most concentrated spray on the smallest mature fruit-bearing tree in commercial production. Additionally, methods of adjusting for tree size as reflected in agricultural practices should be provided. Some examples as recommended by the Extension Service will be provided in the next revision of the Residue Chemistry Pesticide Assessment Guidelines (Subdivision O: Residue Chemistry, 40 CFR §158.125).

b. Special Modes

For special modes of application (aircraft, ultra low volume [ULV], mist sprays), the Use Directions should include the spray concentration, the active ingredient per acre, and the spray volume per acre. This is necessary since the volumes of solutions used in these cases are generally much less than the usual spray solutions.

2. Postharvest Applications

a. Fumigation

Fumigation generally involves the chemical treatment of crops which have been harvested and are being stored or are already in storage. The dosages may be expressed in terms of weight of fumigant per volume of storage space (i.e., pounds active ingredient per 100 cubic feet), or weight of fumigant per unit weight of commodity treated (pounds active ingredient per 1000 pound grain) or weight of fumigant per unit area and depth of preplant field treatment. Other factors should also be considered. The factors include time of exposure, temperature, pressure, geometry and airtightness of containers, and aeration procedures which include time of aeration.

b. Miscellaneous

The general standards for the Directions for Use are

not applicable to certain specialized processes. For example, such processes include the manufacture of impregnated fruit wraps to control fungus diseases, or processes in which pesticides are applied postharvest to fruits, such as in a wax coating. A complete description of the process, including quality control measures and directions for disposal of spent dip solutions or runoff, should be included in the Proposed Use Section of a petition.

3. Animal Treatments

The uses on animals occur in the form of tags, backrubs, dusts, dips, and wetting sprays. The concentration of the pesticide in the treatment solution is the primary consideration. The Use Directions for dips should include instructions for recharging and maintaining a constant solution strength in the dip tank and for the disposal of spent dip solutions. Factors which may affect the deposition of residues on animals should be included in the Use Directions. Some of the factors include the frequency and maximum number of treatments, amount of time that the animal is to be held in the dip tank, the delivery rate of sprays, and the amount of solution to be applied per animal for spot or other specialized treatments.

For the application of pesticides by automatic devices, for example, photoelectric or actuated sprays, or backrubbers, the Use Directions should include discussions on the recharging and placement of devices so that the degree of exposure of the animals may be estimated.

4. Aquatic Uses

Aquatic uses entail the application of a pesticide to flowing water, impounded water, irrigation ditchbanks, dry beds of water conveyance systems, and other aquatic sites.

The mode of application varies and depends on the intended effect of the pesticide. Herbicides for deep-growing submerged weeds may require deposition of slow-release granules on the bottom near the root zone. For this type of treatment, the dosage would be expressed in terms of pounds active ingredient per surface acre. The use of a water-soluble herbicide which acts by direct absorption into the target plant is dependent upon maintaining a certain concentration in the water, and the dosage should be expressed in terms of parts per million in water. The use directions should relate the dosage per surface area to average pond depth.

Specialized equipment may be required for some aquatic herbicide applications. As a result, a detailed description of the equipment and principles involved in the treatment should be included. For example, metered pumping of invert emulsions to the bottom of lakes through weighted hoses may be used. A proposed use of time-released capsules will require information on how the encapsulated material

is placed and the mechanism of the release.

Often some limitations on the minimum distance from a potable water or irrigation intake pipe are needed. Such limitations are needed whenever unacceptable levels of a pesticide chemical occur in water at the intake pipe.

In order to avoid losses of desirable species through oxygen depletion, it is sometimes necessary to treat at intervals only portions of ponds with heavy weed infestations. The label should state what proportions of a pond should be treated per application and the required interval between treatments. If treatments are intended only for pond margins, as opposed to overall broadcast treatment, then it should be so indicated.

Ditchbank treatments are usually made by boom sprayers from trucks. For adequate coverage there is an unavoidable overlap with some direct addition to the water as well as runoff contamination. The label should clearly indicate how such treatments are to be made with minimum contribution of herbicide to the water. A prohibition may be required against cross-ditch spraying.

5. Food-Handling Establishments

The potential exists for the contamination of foods due to pesticide treatment of areas where food is prepared or processed. Therefore, the applicator must have clear Use Directions in order to minimize the contamination of foods.

The Directions for Use should include:

a. The type of establishment that may be treated;

b. The dilution instructions for preparing the working solutions;

c. The spray concentration;

d. The type of application equipment;

e. The mode of application (e.g., directed spray to crevices, baseboards, space spray, etc.);

f. Dosage limitations including cubic and square foot limitations;

g. Frequency of treatment; and

h. Time of treatment (e.g., after-hours in restaurants).

Other information which should be provided, where necessary, are as follows:

a. Sanitation procedures;

b. Removal of food;

c. Covering of dishes and utensils; and

d. Cleanup procedures before food preparation, processing, or serving resumes.

6. Agricultural Premises

Agricultural premise uses include distribution of granular insecticides to feed lots; fogging of dairy barns; installation of impregnated strips in animal barns; and applications of sugarbase bait sprays to walls, stanchions, and other surfaces of barns.

The Use Directions should be sufficiently detailed to permit an evaluation of the potential for residues on milking equipment, exposure to feeds, and drinking and feed troughs, or in meat, milk, and eggs of livestock housed on treated premises.

The Use Directions should state what areas are to be treated, the frequency of treatment, whether animals must be removed at time of treatment, and any other pertinent information.

Dosage for fogging treatments should be expressed in terms of number of installations per unit volume; sprays in terms of concentration of active ingredient in the solution applied; and feed lot applications in terms of weight of active ingredient per unit area.

D. Use Restrictions

Restrictions placed on the use of the pesticide should be clearly written and practical. The following is a summary of the use restrictions commonly on labels, and the information needed to adequately support such restrictions.

1. The maximum number of applications permitted during a growing season should be indicated. Also, the timing of the applications should be noted as well as the intervals permitted between treatments.

2. The interval between the last application and harvest should be indicated. This interval is commonly referred to as the preharvest interval (PHI), and expressed in days. For animal treatments, the interval between the last treatment and slaughter is commonly referred to as the preslaughter interval (PSI) and is usually expressed in days.

3. For crops, the timing of the application may be tied to a stage of crop growth. For example, with cotton the statement "not after first bolls open" is used.

Again, information on the minimum interval from the treatment stage to harvest is needed.

4. Impractical or unrealistic use restrictions should be avoided. Restrictions on the food or feed use of plant parts are practical only when (1) the item remains under the direct control of the grower; (2) the item is not of significant economic importance as a feed item; and, (3) the US customary practice is not to use the item as a feed. For example, a restriction on the feed use of soybean straw is practical because the plant refuse remains under the control of the grower, the item is not of significant economic importance as a feed item and the percentage of US soybean acreage fed as forage is very low. Also, a restriction in the form of a PHI would be practical for pasture grass. Conversely, restrictions on the feed use of corn forage or fodder would be impractical since these are major livestock feed items. While corn forage and fodder are under the control of the grower, the high economic value of the feed items and the overwhelming practice of growers to feed these items make the restriction impractical.

5. The use restrictions should be as specific as possible. For example, a restriction such as "Do not use after lay-by" is indefinite because the "lay-by time" may vary considerably for a given crop. Indefinite terms such as "Do not use on animals being finished for slaughter" are not acceptable. Instead, a specific withdrawal period should be requested by the petitioner.

6. Where use in food-handling establishments is proposed, specific Use Directions to minimize human exposure through residue transfer are needed. Explicit warnings such as "Cover food utensils" and "Do not apply to food contact surfaces" are most useful. However, a general statement such as "Avoid contamination of food" is less useful and therefore of limited effectiveness.